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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/500,478 | 01/28/2005 | Jan Sternby | 02508.0106 | 4522 |
| 22852 | 7590 | 01/18/2008 | EXAMINER | |
| FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413 | | | KIM, SUN U | |
| | | ART UNIT | PAPER NUMBER | |
| | | 1797 | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | |
|------------------------------|----------------------|------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/500,478 | STERNBY ET AL. |
| | Examiner John Kim | Art Unit 1797 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 29 October 2007.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-30 is/are pending in the application.
 4a) Of the above claim(s) 1-11 and 16-26 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 12-15 and 27-30 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 30 June 2004 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date 6/30/04.

4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.
 5) Notice of Informal Patent Application
 6) Other: _____.

1. Applicant's election of Species IV (claims 12-15, 27-30) in the reply filed on 10/29/07 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 1-11 and 16-26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was treated as an election **without** traverse in the reply filed on 10/29/07 as noted above.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 27-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Polaschegg et al (US Patent No. 4,702,829).

Regarding claim 27, Polaschegg et al teach a hemodiafiltration device comprising a blood circuit (104, 110, 106, 114), a fluid circuit (22, 24) and a filter (12) having a semipermeable membrane (14) separating a fluid compartment (16) from a blood compartment (12) provided with means (e.g. connection of 100 to 120) for mixing blood and a cleaning fluid and directing the mixture through the blood compartment (12) and means (66 e.g. ultrafiltrate pump) for applying a pressure gradient across the membrane (14) to create an ultrafiltration into the fluid compartment (16) equal in size to the sum of a flow rate of the cleaning fluid and a desired weight loss rate of the patient wherein a water permeability coefficient of the filter (12) is at least

10 ml/min/mm Hg (see figure; col. 3, line 16 – col. 6, line 65; col. 9, lines 22-63). Recitation of “the cleaning fluid flow rate is at least 1000 ml/min and a ratio between the cleaning fluid flow rate and a blood flow rate is at least 5” is an intended use of the apparatus. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Regarding claim 28, Polaschegg et al teach that the filter is replaced by several filters (44, 78) arranged in series or parallel or a combination thereof (see figure).

5. Claims 29-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Polaschegg et al as applied to claim 27 or 28 above, and further in view of Brugger et al (US Patent No. 6,572,641 B2). Regarding claims 29-30, Polaschegg et al do not suggest a heater for heating blood before it is returned to the patient. Brugger et al teach a blood warming device in connection to a device (60) including hemodiafiltration or ultrafiltration device to heat blood to protect against hypothermia in patients receiving blood and avoids the need for a separate drip chamber (see figure 3; col. 3, lines 20-29; col. 4, line 51 - col. 5, line 2). It would have been obvious to a person of ordinary skill in the art to combine the hemofiltration device with blood warming device of Brugger et al along a path including returning blood to protect against hypothermia in patients receiving blood and avoids the need for a separate drip chamber as suggested by Brugger et al (see col. 3, lines 20-29).

6. Claims 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Polaschegg et al in view of American Journal of Kidney Diseases, Vol. 38, No. 3 (September), 2001, pages 575-579 (hereinafter referred to as Leypoldt et al). Polaschegg et al teach a hemodiafiltration

method comprising a blood circuit (104, 110, 106, 114), a fluid circuit (22, 24) and a filter (12) having a semipermeable membrane (14) separating a fluid compartment (16) from a blood compartment (12) provided with means (e.g. connection of 100 to 120) for mixing blood and a cleaning fluid and directing the mixture through the blood compartment (12) and means (66 e.g. ultrafiltrate pump) for applying a pressure gradient across the membrane (14) to create an ultrafiltration into the fluid compartment (16) equal in size to the sum of a flow rate of the cleaning fluid and a desired weight loss rate of the patient wherein a water permeability coefficient of the filter (12) is at least 10 ml/min/mm Hg (see figure; col. 3, line 16 – col. 6, line 65; col. 9, lines 22-63). Claim 12 essentially differs from the method of Polaschegg et al in reciting that the cleaning fluid flow rate is at least 1000 ml/min and a ratio between the cleaning fluid flow rate and a blood flow rate is at least 5. Leypoldt et al teach that the urea and creatinine mass transfer area coefficients were independent of blood flow rate but increased when dialysate i.e. cleaning fluid was increased from 500 to 800 ml/min in high flux dialyzers (see abstract in page 575). Hence, any dialysate flow rate greater than 1000 ml/min would further enhance mass transfer area coefficients of small solutes and the increased ratio between the dialysate flow rate and the blood flow rate would also enhance mass transfer area coefficients of small solutes for increased removal of small solutes through the membrane in high flux dialyzers. It would have been obvious to one having ordinary skill in the art at the time the invention was made to optimize the dialysate flow rate as well as the ratio between the dialysate flow rate and the blood flow rate in the method of Polaschegg et al to arrive at optimal removal of small solutes by enhancing mass transfer coefficients of small solutes as suggested by Leypoldt et al, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering

the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Regarding claim 13, Polaschegg et al teach that the filter is replaced by several filters (44, 78) arranged in series or parallel or a combination thereof (see figure).

7. Claims 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Polaschegg et al in view of Leypoldt et al as applied to claim 12 or 13 above, and further in view of Brugger et al (US Patent No. 6,572,641 B2). Regarding claims 14-15, Polaschegg et al do not suggest heating blood before being returned to the patient. Brugger et al teach that a blood warming device in connection to a device (60) including hemodiafiltration or ultrafiltration device to heat blood to protect against hypothermia in patients receiving blood and avoids the need for a separate drip chamber (see figure 3; col. 3, lines 20-29; col. 4, line 51 - col. 5, line 2). It would have been obvious to a person of ordinary skill in the art to heat returning blood to a patient in a final dialyzer to protect against hypothermia in patients receiving blood and avoids the need for a separate drip chamber as suggested by Brugger et al (see col. 3, lines 20-29).

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. References cited in PTO-892 teaches various hemodiafiltration device and method.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Kim whose telephone number is 571-272-1142. The examiner can normally be reached on Monday-Friday 7 a.m. - 3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Sample can be reached on 571-272-1376. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/John Kim/
Primary Examiner
Art Unit 1797

JK
1/16/08